

CLAIMS

Amen. A1 1 A polymorphic form of 5-[4-[2-(N-methyl-N-(2-pyridylamino)ethoxy)benzyl]thiazolidine-2,4-dione, maleic acid salt (the Polymorph) characterised in that it provides:

- (i) an infra red spectrum containing peaks at 1752, 1546, 1154, 621, and 602 cm^{-1} ; and/or
- (ii) a Raman spectrum containing peaks at 1751, 1243 and 602 cm^{-1} ; and/or
- (iii) a solid-state nuclear magnetic resonance spectrum containing peaks at 111.9, 114.8, 119.6, 129.2, 134.0, 138.0, 144.7, 153.2, 157.1, 170.7, 172.0 and 175.0 ppm; and/or
- (iv) an X-ray powder diffraction (XRPD) pattern which gives calculated lattice spacings of 6.46, 5.39, 4.83, 4.68, 3.71, 3.63, 3.58, and 3.48 Angstroms.

15 2. A Polymorph according to claim 1, which provides an infra red spectrum substantially in accordance with Figure I.

Amen. A2 3. A Polymorph according to claim 1 or claim 2, which provides a Raman spectrum substantially in accordance with Figure II.

4. A Polymorph according to any one of claims 1 to 3, which provides a solid-state nuclear magnetic resonance spectrum substantially in accordance with Figure III and/or Table I.

25 5. A Polymorph according to any one of claims 1 to 4, which provides an X-ray powder diffraction (XRPD) pattern substantially in accordance with Figure IV and/or Table II.

6. A Polymorph according to any one of claims 1 to 5, in isolated form.

30 7. A Polymorph according to any one of claims 1 to 6, in pure form.

8. A Polymorph according to any one of claims 1 to 7, in crystalline form.

35 9. A process for preparing a Polymorph according to claim 1, characterised in that a solution of Compound (I) in denatured ethanol at an elevated temperature is cooled so as to provide crystallisation of the Polymorph after which the Polymorph is recovered from the denatured ethanol.

10. A pharmaceutical composition comprising an effective, non-toxic amount of a Polymorph according to claim 1 and a pharmaceutically acceptable carrier therefor.

5 11. A Polymorph according to claim 1, for use as an active therapeutic substance.

12. A Polymorph according to claim 1, for use in the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.

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13. The use of Polymorph for the manufacture of a medicament for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.

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14. A method for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof, in a human or non-human mammal which comprises administering an effective, non-toxic, amount of Polymorph to a human or non-human mammal in need thereof.

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Amended
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